REMARKS

Claims 4-8 have been cancelled. Claim 1 has been amended. Support is found in canceled claims 4-6. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Priority

The Examiner states that the earliest effective filing date afforded the instantly claimed invention has been determined to be 07/12/05. Applicants assert that the effective filing date should be 07/12/04 based upon submission of Applicants' priority document.

Applicants assert that the priority claim has been properly made by listing of the priority document on the Declaration/Power of Attorney document which was filed with the application and by submission of a certified copy of the foreign application (see M.P.E.P. 201.14(b)). As this application is the US National phase under 35 U.S.C. § 371, a copy of the certified priority document is conveyed by the International Bureau (PCT Rule 17.2(a)).

Although an English translation of the priority document has not been provided, an English translation of a priority document is not necessary to claim priority, but only to overcome an intervening reference (see M.P.E.P. 201.15).

Applicants respectfully submit that the effective filing date should be taken as 7/12/04, the filing date of Applicants' priority document.

Claim amendments - the claimed invention

Amended claim 1 relates to a jellied pharmaceutical composition for oral administration, comprising a 5-HT_3 receptor antagonist, kappa (κ)-carrageenan and/or iota (ι)-carrageenan, locust bean gum, sodium polyacrylate, and water, having a pH of 7 or less.

Prior to the invention by Applicants, a jellied pharmaceutical composition containing 5-HT_3 receptor antagonist such as granisetron was not known.

Against this background, the present inventors found that when the composition includes 5-HT_3 receptor antagonist, (κ)-carrageenan and/or iota (ι)-carrageenan have the ability to form a

jelly by forming a double helix of the carrageenan. In contrast, as discussed in the present specification at paragraph 0014, lambda (λ)-carrageenan cannot reliably form a jelly when a $5HT_3$ receptor antagonist is present.

Furthermore, the combination of (κ)-carrageenan and/or iota (ι)-carrageenan and locust bean gum as claimed achieves a higher jelly strength and lower syneresis property as discussed in paragraph 0021 of the present specification. In addition, adding sodium polyacrylate to the above components can supplement the jelly strength and the balance of syneresis.

Rejection under 35 U.S.C. § 102(b)

Claims 1,3-4, and 8 are rejected under 35 U.S.C. § 102 (b) as anticipated by Johnson, et al. (US 6,316,027).

This ground of rejection is addressed by incorporation of the limitations of claims 5 and 6, which are not subject to this ground of rejection, into claim 1.

In view of Applicants' amendments, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a) (Johnson, Hai, Fukuchi)

Claims 1-5 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson, et al. (US 6,316,027) in view of Hai (US 6,767,558) and Fukuchi, et al. (Pub. no. US 2005/0175628).

Johnson, et al. differ from the claimed invention in that the preparation of Johnson, et al. is freeze-dried, whereas Applicants claimed pharmaceutical composition is a jelly that contains water.

The Examiner is referred to Johnson, et al. cols. 5-6, bridging paragraph which defines "fast-dispersing dosage form" according to the invention:

> The term "fast-dispersing dosage form" encompasses all the types of dosage forms that are prepared by ***subliming a solvent from a composition or mixture that is in the solid state***. However, it is preferred that the fast-dispersing dosage form is of the type described in U.K. Patent No. 1,548,022, that is, a solid fast-dispersing dosage form comprising a network of the active ingredient and a water-soluble or water-dispersible carrier which is inert towards the active ingredient, ***the network having been obtained by subliming solvent from a composition in the solid state***, that composition comprising the active ingredient and a solution or dispersion of the carrier in a solvent. (emphasis added)

Johnson, et al. teach a network obtained from sublimation of a composition in a solid state. This is clearly different from Applicants' jelly formulation that contains water.

As indicated by the Examiner in the rejection of the claims as anticipated by Johnson, et al. under item 8 on page 3 of the Office Action, Johnson, et al. teach formulations containing granisetron in Example 15 which was prepared by the process described in Example 1. However, consistent with Johnson's generic teaching reproduced above, the method of Example 1 is a freeze-drying process where all water is removed (col. 10, lines 33-36). The compositions described by Johnson, et al. have the advantage that they can disintegrate rapidly in the oral cavity without a large volume of water (see col. 3, lines 30-35 and 53-57).

Accordingly, the "fast-dispersing" pharmaceutical compositions of Johnson, et al. are very different from the jellied pharmaceutical composition of the present invention in dosage form. Applicants' claimed invention is directed to a jelly that is easy to swallow. On the other hand, Johnson, et al. is directed to a fast-dispersing form that will quickly dissolve in the oral cavity with minimal or no swallowing.

Hai Wang does not correct the deficiencies of Johnson, et al. Hai Wang is directed to use of a reductant and does not teach jellied formulations.

Regarding Fukuchi, et al., the Examiner states that "in view of the fact that Johnson, et al. disclose carrageenan, and in view of Fukuchi et al which teaches the use of a combination of iota-carrageenan with kappa-carrageenan, a person of ordinary skill in the art would immediately envisage using as a gelatinizing agent a mixture of κ- and ι-carrageenan (as recited by instant claim 5) in the teaching of Johnson, et al." (Office Action, page 6, paragraph 1).

In response, Applicants assert that one of ordinary skill in the art would not even consider Johnson, et al. as Johnson, et al. is directed to a completely different technology which teaches the exclusion of water by freeze-drying to make a rapidly disintegrating tablet. The dosage form of Johnson, et al. contains no water but does contain pores to allow water to enter quickly once the tablet is in the oral cavity. Water would never be included in the fast-dispersing form of Johnson, et al. because the form would begin to dissolve. The point of the drug delivery of Johnson, et al. is that the tablets begin to dissolve when they are taken into the oral cavity by the patient and not before.

While Fukuchi, et al. teach a jelly formulation, Fukuchi, et al. do not teach a 5-HT_3 receptor antagonist. As discussed above, while Johnson, et al. do teach a 5-HT_3 receptor antagonist, one of ordinary skill in the art in preparing a jelly formulation containing a 5-HT_3 receptor antagonist would not look to Johnson, et al because Johnson, et al. teach a delivery that is opposite to the teaching of the claimed invention.

Furthermore, it was not predictable that a composition containing 5-HT_3 receptor antagonist could form a jelly formulation. As discussed in the specification at page 0014, λ-carrageenan does not reliably form a jelly formulation with 5-HT_3 receptor antagonist. Accordingly it was not predictable that a jelly formulation containing 5-HT_3 receptor antagonist could be produced.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a) (Johnson, Ninomiya)

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Johnson, et al. (US 6,316,027) in further view of Ninomiya, et al. (US 5,932,235).

As discussed above, claim 6 has been incorporated into claim 1. Claim 1 relates to jellied pharmaceutical composition comprising "a 5-HT_3 receptor antagonist, kappa (κ)-carrageenan and/or iota (ι)-carrageenan, locust bean gum, sodium polyacrylate, and water...".

As discussed above, Johnson, et al. do not teach or suggest jellied formulations. The deficiencies of Johnson, et al. are not corrected by Ninomiya, et al.

Ninomiya, et al. teach jellied formulations but do not teach or suggest either 5-HT_3 receptor antagonist or kappa (κ)-carrageenan and/or iota (ι)-carrageenan.

While Johnson, et al. teach a 5-HT_3 receptor antagonist, the combination of Johnson, et al. and Ninomiya, et al. do not lead to the claimed invention as Johnson, et al. teach freeze-dried compositions from which water is excluded. Furthermore, neither reference teaches (κ)-carrageenan and/or iota (ι)-carrageenan in the pharmaceutical composition.

As discussed above, the present inventors found that for 5-HT_3 receptor antagonist compositions, (κ)-carrageenan and/or iota (ι)-carrageenan have the ability to form a jelly by forming a double helix of the carrageenan. Other gelatinizing agents such as lambda (λ)-

carrageenan cannot reliably form a jelly when $5HT_3$ receptor antagonist is present, as discussed in the present specification at paragraph 0014. Accordingly, at the time of the claimed invention, it was not predictable that a $5\text{-}HT_3$ receptor antagonist could be formulated as a jelly composition containing carrageenan.

The presently claimed invention achieves improvement of stabilization of the jellied pharmaceutical composition containing 5-HT3 receptor antagonist as well as ease of administration for good smoothness in the throat, particularly for elderly patients or patients with dysphagia.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a) (Johnson, Zabik & Aldrich)

Claim 7 is rejected under 35 U.S.C. § 103 (a) as being unpatentable over Johnson, et al. (US 6,316,027) in further view of Zabik & Aldrich.

With respect to claim 7, this ground of rejection is believed to be moot in view of Applicants' cancellation of claim 7. Withdrawal of the rejection is respectfully requested.

Double patenting

Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 and 7 of Ninomiya, et al.(US Patent No. 5,932,235) in view of Johnson, et al. (US 6,316,027), Fleming, et al. (Am J. Health System Pharm 52 (5): 514-516, 1995), Quercia, et al, Hai (US 6,767,558), Zabik & Aldrich (J Food Science 30 (5): 795-800, 1965) and FDA Guidance for Industry on Container Closure Systems for Packaging human Drugs and Biologics (May, 1999).

It is asserted that the claims are obvious over US Patent No. 5, 932,235 in light of 6 different secondary references. While the Examiner admits that Ninomiya, et al. do not teach a $5\text{-}HT_3$ receptor antagonist, Johnson, et al. is relied upon for this teaching. However, as discussed above, Johnson, et al. is opposite to the teaching of the claimed invention. Contrary to the jelly formulations of the presently claimed invention, the quickly disintegrating tablet of Johnson et al. excludes water. Accordingly, one of ordinary skill in the art would not look to Johnson, et al for

modifications of a jelly-based drug delivery system. While both Johnson, et al. and the present inventors address similar problem - ease of administration such as for elderly or infirm patients- the two drug delivery vehicles are totally different.

Applicants' claimed invention is directed to a jelly that is easy to swallow. On the other hand, Johnson, et al. is directed to a fast-dispersing form that will quickly dissolve in the oral cavity with minimal or no swallowing.

Fukuchi, et al. is cited for teaching inclusion of water. However, water would never be included in the fast-dispersing form of Johnson, et al. because the form would begin to dissolve prematurely. The point of the drug delivery of Johnson, et al. is that the tablets begin to dissolve only when they are taken into the oral cavity by the patient and not before.

Furthermore, none of the cited references teach that 5-HT_3 receptor antagonist, (κ)-carrageenan and/or iota (ι)-carrageenan have the ability to form a jelly by forming a double helix of the carrageenan. At the time of the claimed invention, it was not predictable that 5-HT_3 receptor antagonist could be formulated as a jelly with carrageenan.

Regarding potassium or calcium salts and use of a light-blocking type container, these features are no longer elements of the presently claimed invention.

In view of Applicants' amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Sept. 25, 2008

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